International Remote Imaging Systems, Inc.
9162 Eton Avenue, Chatsworth, CA 91311
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FEB - 5 2010

510(k) SUMMARY

510(k) Submission: K093861

iQ®200 System with Lamina Cradle

General Information

Date of Submission: 12/03/2009

Trade Name of Device: iQ®200 System with Lamina Cradle

Common Name of Device: Automated Urinalysis System

Classification Name: Automated Urinalysis System,
21 CFR 862.2900, Class I
Microscope, 21 CFR 862.3600, Class I
Automated cell counter (Urine particle counter),
21 CFR 864.5200, Class II

Submitter's Name: Ellen A. Johnston
Sr. Quality Engineer
Iris Diagnostics,
Division of International Remote Imaging Systems, Inc.
9162 Eton Avenue, Chatsworth, CA 91311

Description of Cradle: The iQ Lamina Cradle is a new accessory to be used with the iQ Series of Urine Microscopy Analyzers (K022774). The iQ Lamina Cradle is connected to the iQ Series via a 5V DC USB bus, and is under software control of the desktop computer that is part of the iQ Series. The cradle contains a RFID transceiver and antenna. In simple terms, it recognizes a legitimate IRIS RFID tag embedded in the container label of each 7 liter iQ Lamina Bottle. The software tracks the consumption of iQ Lamina. Visual warning and error messages are displayed as flags in the system software. Audio alerts are communicated through the cradle's speaker. The tracking will alert the operator when a bottle is empty or when a bottle not containing an Iris RFID chip is being used.

Intended Use: The iQ 200 System is an in-vitro diagnostic device used to automate the complete urinalysis profile, including urine test strip chemistry panel and microscopic sediment analysis. Optionally, the iQ 200 Analyzer can be used as a stand-alone unit, or the results from the iQ 200 Analyzer can be combined with other urine

chemistry results received from an LIS. It produces quantitative or qualitative counts of all formed sediment elements present in urine, including cells, casts, crystals, and organisms. A competent human operator can set criteria for auto-reporting and flagging specimens for review. All instrument analyte image decisions may be reviewed and overridden by a trained technologist.

Substantial Equivalence To Predicate Devices:

The iQ 200 System is substantially equivalent under Section 510(k) of the Food, Drug, and Cosmetic Act to The Yellow IRIS Urinalysis Workstation with CHEMSTRIP Reader, the IRIS Flow Microscope, the 900UDx Urine Pathology System, the 939UDx Urine Pathology System, and the Sysmex UF-100. The product codes are LKM, Urine Particle Counter, and KQO, Automated Urinalysis System.

Summary of Technological Characteristics:

The iQ 200 System provides automatic sample handling for automated intelligent microscopy and automatic analyte classification for improved data reporting, presentation and management. Specimens are aspirated by an auto sampler rather than poured manually. Each image is analyzed and assigned a classification by an auto analyte recognition algorithm. Using these classifications and the known observation volume, microscopic analyte concentrations may be automatically reported. If results from a specimen are not auto reported, microscopic examination results are displayed on an independent computer Workstation. Operators can then confirm or modify analyte classification and release reports off-line for enhanced convenience, obviating the need to process a second aliquot for review. Chemistry results from the companion ARKRAY AUTION MAX AX-4280 are automatically consolidated by the Computer Workstation for display and reporting.

Performance Studies:

Not applicable to the addition of Lamina Cradle

Conclusions Drawn From Clinical Tests:

No clinical tests were performed with the addition of the Lamina Cradle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

FEB 05 2010

IRIS International, Inc.
c/o Ms. Ellen Johnston, Sr. Quality Engineer
9172 Eton Avenue
Chatsworth, CA 91311

Re: k093861
Trade/Device Name: iQ® 200 System with iQ® Lamina Cradle
Regulation Number: 21 CFR 864.5200
Regulation Name: Automated Cell Counter
Regulatory Class: Class II
Product Code: LKM, KQO
Dated: January 7, 2010
Received: February 1, 2010

Dear Ms. Johnston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093861

Device Name: iQ 200 System with Lamina Cradle

Indications for Use:

The iQ 200 System is intended for analysis of urine chemistry, specific gravity, and formed sediment elements, which constitutes typical routine urinalysis.

Urinalysis is ordered by physicians as a screening procedure for detection of possible abnormal metabolic or systemic disease, indicated by chemical composition of urine, and of potential renal or urinary tract disease or dysfunction, indicated by urine concentration and by the nature and distribution of urinary formed elements. Urine profile testing is commonly employed in the initial clinical evaluation of patients admitted for hospital care or undergoing physical examinations.

Routine urinalysis is also indicated in diagnosis of patients with possible renal or urinary tract infection, carcinoma, or other injury, as well as for monitoring the status and effectiveness of drug, radiation, or dietary therapy, and of post-surgical or post-therapeutic recovery.

The information produced by the iQ 200 System concerning the composition of patient urines is ordered at the discretion of the physician, and is part of a larger body of laboratory and other test results available to assist the physician in health assessments or differential diagnoses. Routine urinalysis findings are always subject to judgment and interpretation by physicians relative to the patient's overall clinical presentation and history.

August 20, 2002
Harvey Kasdan

Prescription Use ___X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K093861